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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

TO: Ben Limlich
Project Manager
Chemical Review Branch #4
SPRD (TS-768)

THRU: Amy Rispin, Acting Chief SIS
HED (TS-769)

Amy Rispin 1/26/83

SUBJECT: Dioxathion Registration Standard

The purpose of this memo is to discuss issues in the Dioxathion Registration Standard. As these issues have already been covered in the comments of the various HED Branches, the following is a brief review.:

The inert composition of a pesticide is confidential business information unless, of course, the manufacturer choses to make it public on the label or in some other document available to the public. Based on our conservation, it is my understanding that the various references to particular inert ingredients in the Dioxathion Registration Standard are based on label statements and thus may be included in the Standard.

The reference in the Standard that a 90 day feeding study was conducted to determine if dioxathion was oncogenic should be deleted and replaced with suitable reference to the negative NCI oncogenic studies. A 90 day feeding study can not be used as an adequate measure of oncogenicity.

Will include this in the next draft or correction memo

The material which begins "There is a 36 to 1 ratio between the TMRC and the MPI." and ends "The Agency may require additional data to either confirm these figures or recalculate them so that the TMRC/MPI ratio is reduced." should be modified. I suggest the following:

In the initial calculation of the ratio between the TMRC and the MPI, it is the practice of the Agency to make certain assumptions ~~. Thus,~~ if the TMRC exceeds the MPI, the Agency first examines its' assumptions rather than automatically assuming that permitted uses are unsafe. In this case , there is a calculated 36 to 1 ratio between the TMRC and the MPI. The following assumptions have been made in the calculation:

- The level of dioxathion in a particular commodity is numerically equal to the tolerance that has been set for dioxathion in that commodity. In practice, the pesticide level in the actual commodity that the public consumes is often much less than the tolerance level.

- 100 % of the U.S. crop for which a tolerance has been granted is treated with dioxathion. In practice, this is rarely the case.

- In calculating the MPI, 200 is an appropriate Margin of Safety (MOS). Had a similar effect been observed in a chronic study, a MOS of 10 would have been used.

To clarify the relationship between the TMRC and the MPI, additional data are required. In part, this is the reason why chronic studies are required. At such time as the data requested is evaluated, the ratio of TMRC to MPI will be reexamined and a determination made as to what, ~~if any,~~ additional data may be needed.

Ken Bailey

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cc: Charles Frick
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